Remarks

The Office Action

While claims 1 - 47 are mentioned on pages 2, et seq. of the Office Action, it is to be noted that the present continuation-in-part application contains claims 1 - 65, as noted in the Office Action Summary.

In the Office Action of December 3, 2002, claims 1 through 47 were rejected under 35 U.S.C. § 103 on U.S. Patent 3,970,430 Reader, Jr., et al. in view of the admitted prior art in the specification, U.S. Patent 4,692,621 to Passaro et al., and U.S. Patent 3,792,272 to Harte et al.

The claims in this continuation-in-part application were drafted with a view to clearly distinguishing over the cited references, which references were also of record in the parent application. It is respectfully requested that the rejection of the claims be reconsidered and withdrawn in view of the following argument for allowance.

The Invention of Claims 1 - 24 and 42 - 55

Apparatus claims 1 - 24 and method claims 42 - 55 directed to a technique for providing real time analysis of both the nitrogen dioxide (NO_2) content of a patient's breathing gases and the nitric oxide (NO) content of those gases using a particular NO_2 sensor in series with an NO sensor.

As noted in the introductory portions of the present application, it is highly desirable, from the standpoint of safety, to monitor a patient on a breath-by-breath basis, i.e. in real time, for nitrogen dioxide, which is a highly toxic gas, as well as for nitric oxide which, while beneficial in certain concentrations, can be adverse to the health of a patient in other concentrations. Monitoring on a breath-by-breath basis provides an immediate indication of possible conditions injurious to the health of the patient.

The technique of claims 1 - 24 and 42 - 55 meets this need by providing a sensor assembly comprised of a series connected sensor for NO_2 and sensor for NO. The sensor for NO_2 is one employing a semi-conductor radiation source having a maximum wavelength of about 600 nm and a sampling frequency of at least about 10 Hz. A detector

in the NO_2 sensor has a response time of about 200 ms. The claimed sensor assembly is shown in Fig. 4 of the drawing.

The main Reader, Jr. et al. reference describes a technique for measuring the NO_x content of gases, auto exhaust gases and power plant stack gases being given as examples. In the technique of the Reader, Jr. et al. reference, a chemical reaction between the NO_x containing gas and an oxygen containing gas is carried out in a gas tight sample cell. The oxygen containing gas is introduced into the sample cell for this purpose. The details of the chemical reaction are noted in columns 3 and 4 of the Reader, Jr. et al. patent. While the chemical reaction is in progress, the time rate of change of optical absorbance of the contents of the sample chamber is measured along with the absorbance of the gas. See column 8, lines 14-16 of the Reader, Jr. et al. specification. The rate of change of absorbance with respect to time is an indication of the NO concentration of the sample gas and the sum of the time rate of change measurement and absorbance measurement is indicative of the NO_x content of the gas.

The gist of the technique of the Reader, Jr. et al. patent is thus to employ a single sensor-sample cell configuration to sense two physical phenomena, time rate of change and absorbance, of a chemical system undergoing dynamic, reactive change to determine the NO and NO_x content of a gas sample.

The apparatus recited in claims 1, et seq. and method recited in claims 42 et seq., stand in distinct contrast to any teaching or suggestion of the Reader, Jr. et al. reference. As recited in apparatus claim 1, the claimed sensor assembly employs two separate sensors, one for NO_2 and one for NO. The two sensors are connected in series so that the NO sensor is connected to the outlet of the NO_2 sensor. No chemical reaction or reactive agents, such as oxygen, or the like, need be employed in the technique of the present invention.

The technique of the present claims differs in all of general structure (two series connected sensors), detailed structure (sampling frequency) and method (no chemical reaction) from that of the Reader, Jr. et al. reference. In terms of performance, the present claims call for a detector providing an output in a response time of 200 ms. This provides a

real time output for the breathing of a patient that typically occurs at a rate of 14 to 18 breaths per second. The Reader, Jr. et al. reference suggests that measurements be preferably made after a minute (1,000 ms) or after about a half a minute. See column 8, lines 25-27.

Also, the need to inject a reactive gas and the requirement that the measurements be carried out in a subsequent chemically dynamic condition in the gases, would seriously impede, if not prevent, adoption of the technique of the Reader, Jr. et al. reference in the real time gas measurement of a breathing patient.

While it is known to photometrically determine the NO_2 content of a gas using radiation of a wavelength falling within the NO_2 absorption band, as noted in the introductory portions of the Reader, Jr. et al. patent the claims of the present application are not directed simply to this aspect but rather, they call for series connected sensors, specific characteristics of the radiation source in terms of maximum wave length, minimum sampling frequency, and a specified response time for the detector.

In view of the shortcomings of the Reader, Jr. et al. reference, noted above, with respect to this subject matter, the reference is devoid of any teaching or suggestion the invention defined in claims 1 through 24 and 42 through 55.

The secondary admitted prior art, Passaro et al. reference and Harte et al. reference do not overcome the shortcomings of the main Reader, Jr. et al. reference with respect to the features of the claimed invention.

The secondary Passaro et al. patent shows an infrared gas analyzer for measuring gases such as carbon dioxide or anesthetics in the breathing gases of a patient.

While it would be theoretically possible to employ the structure of the Reader, Jr. et al. reference in the breathing gas environment of Passaro et al., the need to periodically seal the sample cell, and the time required to inject the reagent gas in the sample cell and allow the chemical reaction to proceed raises a significant, if not total, impediment to such an arrangement.

There is nothing in the Harte et al. or Reader, Jr. et al. patents teaching or suggesting the use of a modulated light source in the structure of the latter. The examples

given in the Harte et al. reference are to non-reactive situations and there is no indication that a modulated light source would be suitable for the chemically dynamic situation employed by the Reader, Jr. et al. reference.

Claims 1 - 24 and 42 - 55 are thus deemed to define subject matter patentable over the applied references. Withdrawal of the rejection of these claims is respectfully requested.

The Invention of Claims 25 - 41 and 56 - 65

Apparatus claims 25 - 41 and method claims 56 - 65 are directed to a method for determining the nitrogen dioxide (NO_2) content of a patient's breathing gases using alternately operable radiation sources.

The subject matter of claims 25 - 41 and 56 - 65 comprises the NO_2 sensor assembly shown in Fig. 8 having a first semi-conductor radiation source emitting radiation absorbable by NO_2 of up to about 600 nm and a second semi-conductor radiation source producing radiation of a wave length that is minimally absorbed by NO_2. The first and second radiation sources are alternately energized at a sampling frequency, as shown in Fig. 9. Claim 56 has been amended at line 10 to clearly note this feature and to bring the language of that line into conformity with the language of line 12. The alternative operation of the radiation sources provides an output indicative of the NO_2 content of a patient breathing gas sample, as shown in Fig. 10. The claimed approach enhances the sensitivity and signal quality of the NO_2 sensor assembly.

There is no teaching or suggestion in the references of alternately energized light sources as called for in claims 25 and 56. Rather, the Reader, Jr. et al. structure utilizes only a single light source 25 and a beam splitter 27. The Passaro et al. reference utilizes a single light source and a rotating filter wheel. The Harte et al. reference also utilizes only a single light source (30) and also employs a rotating chopper wheel.

None of the references in any way teach or suggest the use of two light sources and the alternating operation of those light sources. Claims 25 - 41 and claims 56 - 65 are clearly patentable over the applied references.

Conclusion

In view of the foregoing, claims 1-24 and 42-55 and 25-41 and 56-65 are deemed to define subject matter patentable over the applied references. Withdrawal of the rejection of these claims, and passage of the application to allowance, is respectfully requested.

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